CLAIMS

What is claimed is:

1. A method for preparing a suspension of a pharmaceutically-active compound, the solubility of which is greater in a water-miscible first organic solvent than in a second solvent which is aqueous, the process comprising the steps of:

(i) dissolving a first quantity of the pharmaceutically-active compound in the water-miscible first organic solvent to form a first solution;

(ii) mixing the first solution with the second solvent to precipitate the pharmaceutically-active compound to create a presuspension; and

(iii) seeding the first solution or the second solvent prior to the or the presuspension after the mixing step.

2. The method of claim 1 wherein the step of precipitating the pharmaceutically-active compound comprises the step of precipitating the compound in a form selected from the group consisting of a supercooled liquid, an amorphous particle, a semicrystalline particle and a crystalline particle.

3. The method of claim 2 further comprising the step of adding energy to the presuspension.

4. The method of claim 3 wherein the adding-energy step comprises the step of subjecting the presuspension to high energy agitation.

5. The method of claim 3 wherein the adding-energy step comprises the step of adding heat to the presuspension.

6. The method of claim 3 wherein the energy-addition step comprises the step of exposing the presuspension to electromagnetic energy.

7. The method of claim 6 wherein the step of exposing the presuspension to

electromagnetic energy comprises the step of exposing the presuspension to a laser beam.

8. The method of claim 1 further comprising the step of forming a desired polymorph of the pharmaceutically active compound.

9. The method of claim 8 wherein the step of seeding comprises the step of using a seed compound.

10. The method of claim 9 wherein the seed compound is the desired polymorph of the pharmaceutically-active compound.

11. The method of claim 9 wherein the seed compound is a compound other than the desired polymorph of the pharmaceutically-active compound.

12. The method of claim 11 wherein the seed compound is selected from the group consisting of: an inert impurity; and an organic compound with a structure similar to that of the desired polymorph.

13. The method of claim 9 wherein the seed compound is added to the first solution.

14. The method of claim 9 wherein the seed compound is added to the second solvent.

15. The method of claim 9 wherein the seed compound is added to the presuspension.

16. The method of claim 8 wherein the step of forming a desired polymorph comprises the step of forming a seed compound in the first solution.

17. The method of claim 16 wherein the step of forming the seed compound in the first solution comprises the step of adding the pharmaceutically-active compound in sufficient quantity to exceed the solubility of the pharmaceutically-active compound in the first solvent to create a

supersaturated solution.

18. The method of claim 17 wherein the step of forming the seed compound in the first solution further comprises the step of treating the supersaturated solution.

19. The method of claim 18 wherein the step of treating the supersaturated solution comprises the step of aging the supersaturated solution.

20. The method of claim 1 wherein the seeding step comprises the step of using electromagnetic energy.

21. The method of claim 20 wherein the electromagnetic energy is dynamic electromagnetic energy.

22. The method of claim 20 wherein the electromagnetic energy is a laser beam.

23. The method of claim 20 wherein the electromagnetic energy is radiation.

24. The method of claim 1 wherein the step of seeding comprises the step of using a particle beam.

25. The method of claim 1 wherein the step of seeding comprises the step of using an electron beam.

26. The method of claim 1 wherein the step of seeding comprises using ultrasound.

27. The method of claim 1 wherein the step of seeding comprises using a static electrical field.

28. The method of claim 1 wherein the step of seeding comprises using a static magnetic

field.

29. The method of claim 1 further comprising the steps of forming particles having an average effective particle size less than about 2μm.

30. A method for preparing a suspension of a pharmaceutically-active compound, the solubility of which is greater in a water-miscible first organic solvent than in a second solvent which is aqueous, the process comprising the steps of:

(i) dissolving a first quantity of the pharmaceutically-active compound in the water-miscible first organic solvent to form a first solution;

(ii) mixing the first solution with the second solvent to precipitate the pharmaceutically-active compound to create a presuspension; and

(iii) providing a seed compound to the first solution or the second solvent or the presuspension.

31. The method of claim 30 further comprising the step of adding energy to the presuspension to provide particles having an average effective particle size of less than about 2 μm.

32. The method of claim 30 further comprising the step of forming a desired polymorph of the pharmaceutically active compound.

33. The method of claim 32 wherein the step of seeding comprises the step of providing a seed compound.

34. The method of claim 33 wherein the seed compound is the desired polymorph of the pharmaceutically-active compound.

35. The method of claim 33 wherein the seed compound is a compound other than the desired polymorph of the pharmaceutically-active compound.

36. The method of claim 35 wherein the seed compound is selected from the group consisting of: an inert impurity; and an organic compound with a structure similar to that of the desired polymorph.

37. The method of claim 33 wherein the seed compound is added to the first solution.

38. The method of claim 33 wherein the seed compound is added to the second solvent.

39. The method of claim 33 wherein the seed compound is added to the presuspension.

40. The method of claim 32 wherein the step of forming a desired polymorph comprises the step of forming a seed compound in the first solution.

41. The method of claim 40 wherein the step of forming the seed compound in the first solution comprises the step of adding the pharmaceutically-active compound in sufficient quantity to exceed the solubility of the pharmaceutically-active compound in the first solvent to create a supersaturated solution.

42. The method of claim 41 wherein the step of forming the seed compound in the first solution further comprises the step of treating the supersaturated solution.

43. The method of claim 41 wherein the step of treating the supersaturated solution comprises the step of aging the supersaturated solution.

44. A method for preparing a suspension of a pharmaceutically-active compound, the solubility of which is greater in a water-miscible first organic solvent than in a second solvent which is aqueous, the process comprising the steps of:

(i) adding a quantity of the pharmaceutically-active compound to the first organic solvent to create a supersaturated solution;

(ii) aging the supersaturated solution to form detectable crystals to create a seeding mixture; and

(iii) mixing the seeding mixture with the second solvent to precipitate the pharmaceutically-active compound to create a presuspension.

45. The method of claim 44 wherein the pharmaceutically-active compound of the presuspension is in a form selected from the group consisting of a supercooled liquid, an amorphous particle, a semicrystalline particle and a crystalline particle.

46. The method of claim 45 further comprising the step of converting the compound in the presuspension to a desired polymorph.

47. The method of claim 46 wherein the step of converting the compound of the presuspension comprises the step of adding energy to the presuspension.

48. The method of claim 47 wherein the adding-energy step comprises the step of subjecting the presuspension to high energy agitation.

49. The method of claim 47 wherein the adding-energy step comprises the step of adding heat to the presuspension.

50. The method of claim 47 wherein the adding-energy step comprises the step of exposing the presuspension to electromagnetic energy.

51. The method of claim 47 wherein the step of exposing the presuspension to electromagnetic energy comprises the step of exposing the presuspension to a laser beam.

52. The method of claim 44 further comprising the steps of: adding energy to the pre-suspension to form particles having an average effective particle size of less than about 2μm.

53. A method for preparing a suspension of a pharmaceutically-active compound, the solubility of which is greater in a water-miscible first organic solvent than in a second solvent which is aqueous, the process comprising the steps of:

(i) adding a quantity of the pharmaceutically-active compound to the first organic solvent to create a supersaturated solution;

(ii) treating the supersaturated solution to form a detectable crystal to create a seeding mixture; and

(iii) mixing the seeding mixture with the second solvent to precipitate the pharmaceutically-active compound.

54. The method of claim 53, wherein the treating step comprises aging.

55. The method of claim 53, wherein the treating step comprises adding a surfactant.

56. The method of claim 53, wherein the treating step comprises adding a crystallization modifier.

57. The method of claim 53, wherein the treating step comprises dropping the temperature.

58. The method of claim 53, wherein the treating step comprises using a laser beam.

59. The method of claim 53, wherein the treating step comprises using radiation.

60. The method of claim 53, wherein the treating step comprises using a particle beam.

61. The method of claim 53, wherein the treating step comprises using an electron beam.

62. The method of claim 53 wherein the treating step comprises using ultrasound.

63. The method of claim 53 wherein the treating step comprises using a static electrical field.

64. The method of claim 53, wherein the treating step comprises using a static magnetic field.

65. A composition of matter of a polymorphic pharmaceutically-active compound in a desired polymorphic form essentially free of an unspecified polymorphic form.

66. The composition of claim 65 wherein the pharmaceutically-active compound is itraconazole.